

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

***APPLICATION NUMBER:***

**76268**

**APPROVAL LETTER**

JUL 26 2002

Jerome Stevens Pharmaceuticals, Inc.  
Attention: Ronald Steinlauf  
60 DaVinci Drive  
Bohemia, NY 11716

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated October 29, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Digoxin Tablets USP, 0.125 mg (125 mcg) and 0.25 mg (250 mcg).

Reference is also made to your amendments dated March 11, July 1, and July 22, 2002.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Digoxin Tablets USP, 0.125 mg and 0.25 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Lanoxin<sup>®</sup> Tablets, 0.125 mg and 0.25 mg, respectively, of Glaxo Wellcome, Inc.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

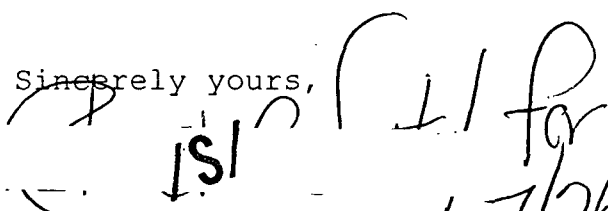
Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FDA 2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

  
Gary Buehler  
Director

Office of Generic Drugs  
Center for Drug Evaluation and Research

7/26/2002